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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,030	06/29/2001	J. Norman Hansen	108172-00058	5493

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ARENT FOX KINTNER PLOTKIN & KAHN
1050 CONNECTICUT AVENUE, N.W.
SUITE 400
WASHINGTON, DC 20036

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/30/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,030	HANSEN, J. NORMAN	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7,8,15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,8,15 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment of 3/26/2003 is acknowledged. Claims 4, 6, 16 and 9-14 have been cancelled, rendering any rejections of these claims as moot. New claims 24-25 have been submitted; claims currently pending and under consideration are 1-3, 5, 7-8, 15 and 17-25.

Specification

The objection to the disclosure for recitation of application number is withdrawn, based upon the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-3, 5, 7-8, 15 and 18-23 under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn, based upon the amendment.

Claim 23 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record. It is acknowledged that Applicant has shown activity of the sublancin peptide against a wide variety of gram-positive bacteria & thus has description for the generic claims; however, it is noted that claim 23 is directed to

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decontaminating a *Bacillus anthracis* spore containing area. The technical difficulty of decontaminating an environment contaminated with such spores is widely known in the art (see, e.g., the discussions by Ingelsby *et al.* pages 2249-2250, and by Hawley *et al.*, pages 243-245). For this reason, it is deemed that the disclosure of the specification is insufficient to describe a method of decontaminating a *Bacillus anthracis* spore containing area. Evidence of successful decontamination of these specific spores could overcome this rejection.

Applicant's arguments filed 3/2002 have been fully considered but they are not persuasive. It is stated that the attached internet article states that *B. cereus* can be used as a substitute for anthrax. And thus the specification is enabling. The Examiner did not only reject for enablement, but also for lack of written description. Further, the reference states "Anthrax bacteria are too dangerous to use in initial studies, so the Center used *B. cereus* a closely related, but nearly harmless bacterium,. *B. cereus* is commonly used as a model system for the study of Anthrax." The reference seems to suggest that *B. cereus* can be used in initial studies of drug screening because of the danger of using anthrax, those initial studies would indicate which compounds may be promising for testing on anthrax.. Such a model system, which can be performed on an ordinary lab bench, however, does not indicate that a compound can be successfully used on anthrax, only that a certain compound is a candidate for testing in a high containment facility upon the anthrax bacteria themselves. The Examiner maintains that Applicant has not described effectiveness of sublancin upon *B. anthracis*..

Claim 23 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. What is not described in cannot be considered enabled

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 15-22 remains rejected under 35 U.S.C. 103(a) as being unpatentable over PAIK *et al.* in view of OLSEN *et al.* (US patent 6143498) The PAIK *et al.* reference teaches the production of the antimicrobial peptide sublancin-168 and the activity of the peptide against a variety of different bacteria that are either Gram positive or negative; it does not teach the addition of a his-tag to that peptide for simple purification. Olsen *et al.* teach the addition of a his-tag to an antimicrobial peptide in order to facilitate purification, but are silent on sublancin. They state in Example 1 that a specific commercially available expression vector contains six codons for histidine and that the elements of the vector are so arranged that the histidine residues are attached to the carboxy end of an expressed polypeptide. It is noted that their construct is such (see column 20, lines 48-65) that several codons are placed between the his codons and the carboxyl end of the peptide; thus their expressed his-tag polypeptide contains a spacer between the carboxyl end of their peptide and the his codons. One of ordinary skill in the art at the time of the invention would have expected to utilize the same system as Olsen *et al.* in order to obtain other His-Tag antimicrobial peptides, such as the sublancin 168 of PAIK

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et al., with a reasonable expectation of success. The Examiner notes that the specification states on page 6, lines 17-22 that attempts to affinity label other lantibiotics were unsuccessful; however, no other information is presented. The Examiner notes that epidermin has been affinity labeled with a his tag (KUPKE *et al.*).

Applicant's arguments filed 3/26/2003 have been fully considered but they are not persuasive. It is stated that Applicant has obtained unexpected results because of difficulties in labeling the end of a lantibiotic and retaining activity. Applicant has not addressed the success of Kupke *et al.* in labeling the lantibiotic epidermin with a histidine tag. Further, Applicant has submitted a terminal disclaimer, thus agreeing with the Examiner that the instant claims are obvious in light of sublancin itself. The instant invention cannot be both unexpected and obvious over the peptide itself.

Double Patenting

The terminal disclaimer filed on 3/26/2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of as being unpatentable over claims 1-9, 11-14, and 30 of copending Application No 09/462478 (now US patent 6541607. has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

No claims are allowed

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).


Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.


Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

July 28, 2003